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EXAMINER

PREBILIC, PAUL B

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/809,349  
Filing Date: March 26, 2004  
Appellant(s): ASIUS ET AL.

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Burton Amernick  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed February 27, 2008 appealing from the Office action mailed August 28, 2007.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The Appellant's statement of the status of amendments after final rejection contained in the brief is not entirely correct. An amendment after final rejection was filed on December 7, 2007. The amendment was actually a request for reconsideration that was considered.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The Appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

5,356,629	SANDER et al	10-1994
5,470,852	SUPERSAXO et al	11-1995
5,599,852	SCOPELIANOS et al	02-1997

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sander et al (US 5,356,629) in view of Supersaxo et al (US 5,470,582). Sander meets the claim language where the microparticles of polymers of non-animal origin are disclosed on column 3, line 48 to column 4, line 11 of Sander, the hydrogel precursor as claimed is the gel of the matrix before it is wetted; see column 2, lines 35-56 and the dried state is suggested by the "prior to being wetted" state; see column 3, lines 38-47. However, Sander fails to clearly disclose that the matrix is completely dry as suggested by the freeze-dried state. Supersaxo, however, teaches that it was known to freeze dry or dry similar materials in order to stabilize them for storage; see column 2, lines 19-26 and column 4, lines 40-46. Therefore, it is the Examiner's position that it would have

been obvious to freeze-dry the Sander matrix for storage or for the same reasons that Supersaxo does the same.

With regard to claim 11, since the same material as claimed is disclosed by Sander, the Examiner asserts that it inherently and necessarily has the same bioresorbtion rate. Furthermore, it is noted that the range does not clearly have a lower limit because within about one to about three years can be interpreted as meaning the same as up to about three years.

With regard to claim 15, the Board and Appellant are directed to column 2, lines 57-66 of Sander.

With regard to claim 16, the Board and Appellant are directed to the paragraph bridging columns 2 and 3 of Sander.

With regard to claims 17 to 19, Supersaxo teaches the concept of including cryoprotectants and surfactants where mannitol and a surfactant are utilized; see column 4, liners 47-54. Therefore, it is the Examiner's position that it would have been obvious to utilize the same in Sander for the same reasons that Supersaxo utilizes the same.

Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sander and Supersaxo as applied to claims 10-19 and 23 above, and further in view of Scopelianos et al (US 5,599,852). Sander as modified by Supersaxo fails to disclose the use of a kit, vial, or syringe as claimed. However, Scopelianos teaches that is was known to the art to include a kit with a syringe; see the abstract, column 1, lines 48-57, column 8, line 24 et seq., and the claims. Therefore, it is the Examiner's position that it

would have been *prima facie* obvious to utilize a kit with a syringe and vial to store the product for the long term, as suggested by Supersaxo, and to make it easier to use the product.

## **(10) Response to Argument**

### **ISSUE A**

The Appellant argues that Sanders refers to putties that are not considered to be gels to one of ordinary skill in the art; see page 6 of the Brief. However, the present claims only require "a hydrogel precursor" or a "freeze-dried" composition that contained a gel so this argument is not clearly directed to the claimed invention. Moreover, the Appellant has not particularly limited the claims to a particular definition for a gel because Appellant merely argues that a "gel is typically defined as . . . a jelly-like product." (emphasis added). Furthermore, Sander utilizes the same specific material, "cellulose ether", as the Appellant (see dependent claims 13 and 14) so Sander must inherently be a gel precursor to the extent required by the present claims. Additionally, Sander does not only describe the semisolid material as a "putty" but also describes the material as "*a highly viscous substance which is yet flowable to some extent such as a gel, paste, putty or clay*"; see column 2, lines 52-53.

Next, the Appellant argues that the parent application and the reissue therefor were limited to a particular meaning for "gel" that precluded utilizing putties. However, the Examiner asserts that the file wrapper history or estoppel in the parent application does not carry over to that of the present application. Furthermore, the definition

provided by the Appellant in this Brief is clearly an exemplary one in that the Appellant states that a “gel is typically defined as”; there is no special definition in the specification. Finally, the Appellant has not claimed a gel but merely “a hydrogel precursor” (see claim 10, line 7) or a composition that contained a gel before it was freeze dried (see claim 23).

On page 7 of the Brief, the Appellant argues that Sander does not disclose a material that is reconstitutable. However, Sander utilizes the same material, “cellulose ether”, as the Appellant does so it is inherently reconstitutable to the extent required. Furthermore, Sander discloses a step of reconstituting the compositions by wetting them to make them more workable; see column 3, lines 38-47.

Next, the Appellant argues that Sander does not disclose microparticles; see page 7, third paragraph of the Brief. However, the size that the term “microparticles” requires is not clear but has been understood to mean relatively small particles. Since the particles utilized by Sander can be as small as 100 microns (see column 4, lines 31-39), the Examiner asserts that Sander discloses “microparticles” even though they are not called by that name.

In response to the Appellant’s argument that the Sander cellulose derivatives function as matrix materials not gelling agents as claimed, the Examiner asserts that the material of Sander is the same as that claimed so it inherently functions in the same manner; see MPEP 2112.01, subsections I and II that are incorporated herein by reference.

The Appellant also argues that the Sander material will harden as a bone graft material once implanted; see the last paragraph on page 7 of the Brief. However, Sander states the contrary in the passage from column 1, line 56 to column 2, line 32 where Sander states that the composition "*will not set into a rock hard material like plaster of paris which, when wetted, begins to set and lose workability within five to ten minutes. Therefore, the composition of the present invention retains workability or moldability characteristics for an extended period of time after being wetted, resulting in improved overall handling characteristics and ability to be shaped upon implantation into a bone defect site.*" Furthermore, contrary to the Appellant's position, the Examiner does not see how the Sander material will be dried when it within the body surrounded by bodily fluids.

## **ISSUE B**

The Appellant relies on the traversal of the Sander in view of Supersaxo rejection (ISSUE A) to suggest the untenability of the present rejection. Therefore, the Examiner asserts that the present rejection should stand or fall with the rejection of ISSUE A.

## **(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.



Art Unit: 3700

Respectfully submitted,

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